# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference PBA/P089323PWO | **FOR FURTHER ACTION** | See Form PCT/IPEA/416 |
|---|---|---|
| International application No. PCT/GB2004/001199 | International filing date *(day/month/year)* 18.03.2004 | Priority date *(day/month/year)* 18.03.2003 |
| International Patent Classification (IPC) or national classification and IPC G01N33/53, G01N33/543, G01N33/76 | | |
| Applicant PLATFORD DIAGNOSTICS LIMITED et al. | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

| | | |
|---|---|---|
| ☒ | Box No. I | Basis of the opinion |
| ☐ | Box No. II | Priority |
| ☐ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☒ | Box No. VII | Certain defects in the international application |
| ☐ | Box No. VIII | Certain observations on the international application |

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 18.01.2005 | 30.05.2005 |
| Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Komenda, P Telephone No. +49 89 2399-2777 |

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/001199

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

| | |
|---|---|
| **Description, Pages** | |
| 1-21 | as originally filed |
| **Claims, Numbers** | |
| 1-16 | received on 20.01.2005 with letter of 18.01.2005 |
| **Drawings, Figures** | |
| 1-3 | as originally filed |

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/001199

## Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 1-16 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-16 |
| Industrial applicability (IA) | Yes: | Claims | 1-16 |
| | No: | Claims | |

2. Citations and explanations (Rule 70.7):

**see separate sheet**

## Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Section V:**

Reference is made to the following documents:

D1: WO 00/33063 A
D2: WO 90/09596 A
D3: US 2002/187071 A1
D4: EP-A-0 321 736

**N:** Document D1 represents the nearest available prior art and reveals a sample testing device comprising features a) (in part) to feature g) recited in independent claim 1 (see figures 1 and 2 and corresponding description). It should be mentioned here, that a "capillary tube" (claim 1) appears to be comparable to "travel by capillary action" (D1, cf. page 10, bottom). Document D1 does not disclose the use of a reagent system which causes agglutination in the capillary tube (Article 33(2) PCT). Note that the "detection arrangements" must only **be suitable for** detecting the presence of liquid which is also the case for the detection arrangement of D1 (see in this respect also present claim 12).

The same distinguishing feature is also present in dependent claims 2-16.

**IA:** The testing device of D1 may be used for detecting the levels of an analyte in a biological sample, using specific binding partners for the analyte. The use of the testing device of D1 is not particularly restricted to specific analytes, to the contrary, "a wide variety of species" may be envisaged (paragraph bridging pages 7 and 8). The testing device according to claim 1 may also be used for detecting the levels of an analyte in a biological sample, however, by causing agglutination in the presence of the analyte.
The technical problem to be solved is thus to provide a testing device like in D1 comprising another, alternative type of assay system.
Agglutination assay systems are well known in clinical testing of biological samples, in particular in combination with capillary type testing devices (see e.g. D2). It would thus appear obvious for the skilled person to consider the application of an agglutination causing agent (or any other alternative assay system) in the device of

D1 in order to solve the problem posed. The subject-matter of claim 1 thus appears to lack an inventive step as required by Article 33(3) PCT.

At present it is not apparent for which technical problem the features of the dependent claims would provide an inventive solution. The particular type of power source and capillary pathway, the details of the agglutination assay and the presence of flow regulating material is either known from D1 or common for the skilled person (see e.g. D3/D4) and would thus appear to add nothing inventive to present independent claim 1.
Although document D2 relates to blood coagulation assay it appears for instance that any known coagulation assay could be performed by the device of D1 (cf. claim 9). Similar considerations apply to the location of the dissimilar electrodes of the power source.

**IA:** Industrial applicability is acknowledged (Article 33(4) PCT).

**Section VII:**

1. The claims are not provided with reference signs.

CLAIMS

1. A sample testing device for testing for the presence of a component of interest in a liquid sample, the device comprising:

(a) at least one capillary tube which has an upstream end and a downstream end and which incorporates a reagent system capable of causing agglutination with said component to be detected (the test capillary);

(b) preferably, but optionally, at least one capillary tube having an upstream end and a downstream end (the control capillary);

(c) a sampling region to which the liquid sample is applied and from which the sample is able to enter the upstream ends of the test capillary(s) and if present the control capillary(s);

(d) a power source;

(e) detection arrangements electrically associated with said power source for detecting the presence of liquid at a downstream region of said testing capillary(s) and if present the control capillary(s);

(f) display means operated by said power source for indicating the result of the test; and

(g) signal processing means associated with the power source, detection arrangement and display means for evaluating the result of the test and providing said result on the display means.

2. A device as claimed in claim 1, wherein the power source comprises electrodes of dissimilar metals provided at the sampling region of the device; said electrodes being adapted to generate a current when liquid sample is applied to said region.

3. A device as claimed in claim 2, wherein the electrodes of the dissimilar metals alternate with each other.

4. A device as claimed in anyone of claims 1 to 3, wherein the signal processing means incorporates a timing arrangement which is initiated by the liquid sample to the sampling region and wherein detection for the presence of liquid at the downstream regions of the test capillary and control capillary (if present) is effected within a predetermined time as governed by the timing arrangement.

5. A device as claimed in anyone of claims 1 to 4, wherein the reagent binding system comprises beads on which is immobilised a binding partner for said component.

6. A device as claimed in claim 5, wherein the binding partner is an antibody.

7. A device as claimed in anyone of claims 1 to 6, wherein the agglutination reagent system comprises a binding partner for said component immobilised on the walls of the test capillary.

8. A device as claimed in claim 7, wherein the binding partner immobilised on the wall of the test capillary is an antibody.

9. A device as claimed in anyone of claims 1 to 8, wherein the agglutination reagent system is capable of causing agglutination in the presence of hCG.

10. A device as claimed in anyone of claims 1 to 9, wherein the or each test capillary is formed by a co-operating plate and lid arrangement, said plate being formed with channels which become capillary tubes on location of the lid.

11. A device as claimed in claim 10, wherein downstream regions of the or each capillary tube have apertures and the or each detection arrangement is provided beneath a said aperture.

12. A device as claimed in any one of claims 1 to 11, wherein the or each detection arrangement comprises a pair of electrodes across which a potential difference may be applied.

13. A device as claimed in any one of claims 1 to 12 wherein the test capillary incorporates a particulate material to enhance the change in flow rate.

14. A device as claimed in claim 13 wherein said material is an inert particulate material.

15. A device as claimed in claim 14 wherein said inert particulate material is silica or bentonite.

16. A device as claimed in claim 13 wherein said material is a swellable polymer.